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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,729	10/29/2003	Scott Freeberg	279.652US1	6340
21186 7590 01/30/2008 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER HOLMES, REX R	
			ART UNIT 3762	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/696,729

Applicant(s)

FREEBERG, SCOTT

Examiner

Rex Holmes

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3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Regarding claim 11, Applicant argues that Scheiner does not teach a processor to evaluate each signal and calculate a confidence level. The examiner respectfully disagrees. Scheiner clearly shows in figure 2 that the signals are processed and then it is determined if the signal has signs of hypotension (240). The output from element 240 is a confidence level.
2. Regarding claim 21, Applicant further argues that Scheiner does not teach a processor adapted to generate a code based on a first ventilation signal, a second ventilation signal and an acceleration signal. It is noted that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. In the instant case, Scheiner discloses a processor and sensing capabilities that are capable of performing the stated task. Scheiner processor that uses both the thoracic impedance and a secondary component that is a accelerometer signal (Col. 6, ll. 37-44).
3. Regarding claims 1, 14, 25, 29, 46 and 53, Applicant further argues that Scheiner only finds a relationship to the impedance values and not to the ventilation rates. It is noted that transthoracic impedance is proportional to respiratory rate. Thus the relationship between the impedances and the respiratory component are equivalents. Further the relationship that is found between the impedances is equal to the relationship found between the respiratory components, and since it is this relationship

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that is being used to generate the code, the system of Scheiner anticipates the claims of the instant application.

4. Regarding claims 11, Applicant argues that Daum does not teach a processor adapted to calculate a confidence level and/or adapted to identify the relationship between impedances. Daum discloses that after it senses the signals it further scales the signals. The scaling of the signals is the calculated confidence level.

5. Regarding claims 1, 14, 25, 29, 46 and 53, Applicant further argues that Daum only finds a relationship to the impedance values and not to the ventilation rates. It is noted that transthoracic impedance is proportional to respiratory rate. Thus the relationship between the impedances and the relationship between the respiratory components are equivalents (Col. 1, ll. 35-48).

6. Regarding claim 11, Applicant argues that Wang does not teach a processor to calculate a confidence level. The examiner respectfully disagrees. Wang senses the signal and then checks the integrity of the leads based on this signal. The result of the lead diagnostics is the confidence level (Fig. 11).

7. Regarding claims 1, 14, 25, 29, 46 and 53, Applicant further argues that Wang only finds a relationship to the impedance values and not to the ventilation rates. It is noted that transthoracic impedance is proportional to respiratory rate. Thus the relationship between the impedances and the respiratory component are equivalents (Paragraph 95).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 3-8, 10-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheiner et al. (U.S. Pub. 2002/0147475 hereinafter "Scheiner").

10. Regarding claims 1, 3-6, 10-11, 13-16, 19-21, 24, 29-34 and 53, Scheiner discloses a cardiac rhythm management system that has a current generator, a first pair of electrodes, a second pair of electrodes and a processor capable of identifying the relationship between the two impedances (e.g. ¶ 66; Figs. 9 and 10). Scheiner further discloses the processor monitors the impedance and that based on the impedance the device alters the stimulation (e.g. Claims 1 and 3). The therapy circuit includes a pulse generator and the processor includes a filter to determine thoracic impedance (e.g. "230"; ¶ 36).

11. Regarding claims 7-8, 12, 17-18, 35-36, Scheiner discloses that the system utilizes an acceleration signal and then uses the acceleration signal along with the impedance information to determine the correct stimulation (e.g. Fig. 5).

12. Regarding claims 23 and 55, Scheiner discloses a telemetry circuit (¶ 24).

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13. It is noted that the claims recite elements that are "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. In the instant case, the Scheiner processor uses both the thoracic impedance and a secondary component that is a accelerometer signal to determine the specific therapy and that specific therapy is a code (Col. 6, ll. 37-44).

14. Claims 1-6, 9-11, 13-16, 19-20, 23-26, 28-34, 38-40, 44-46, 51-53 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Daum et al. (U.S. Pat. 7,101,339 hereinafter "Daum").

15. The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

16. Regarding claims 1-4, 6, 9-11, 14, 16, 25-26, 29-32, 38-40, 44 and 51, Daum discloses a system that includes a current generator (Col. 2, l. 1), multiple chamber lead placement (Col. 2, ll. 53-54) of paired electrode leads (Col. 2, l. 64), a processor adapted to identify the relationship between impedances and to monitor the first, second, and possibly third signal (Col. 1, l. 67 & Col. 2, ll. 3-11), a filter to determine frequencies in the ventilation band (Col. 5, ll. 34-36), a therapy output to provide a pacing pulse (Col. 4, ll. 20-21), a generated ventilation signal (Col. 2, ll. 3-11),

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17. Regarding claims 5, 19-20, 28, 33-34, 46 and 52, the system, device and method of Daum is included in a pacemaker/defibrillator and although not explicitly stated, pacemakers and defibrillators inherently have a pulse generator and therapy circuitry.

18. Regarding claims 13 and 15, the system of Daum provides for both left and right heart stimulation and impedance sensing, and thus is inherently creating a transthoracic current field (Col. 2, ll. 50-67).

19. Regarding claim 45, Daum discloses comparing signals and providing a resulting signal that is a correlate of the selected signals (Col. 6, ll. 58-67 & Col. 7, ll. 1-5).

20. Regarding claims 53 and 55, Daum discloses that the system and method can be used internally, externally, or with any type of cardiac rhythm management system and is capable of being configured to a thorax (Col. 2, ll. 50-61). Daum further discloses that the system can utilize cellular telephones or radios (Col. 5, ll. 2-5).

21. Claims 1-4, 6, 9-11, 14, 16, 25-26, 29-32, 38-40, 44 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (U.S. Pub. 2005/0080460 hereinafter "Wang").

22. Wang discloses a method and apparatus for monitoring thoracic impedance in a body using an implantable cardiac device. The device and method include a current generator (e.g. Fig. 2, "214"), a first pair of electrodes in one chamber ("24", "26"), a second pair of electrodes in a second chamber ("17", "21") and a processor to cross-check impedance measurements using two different impedance measurements (e.g. ABSTRACT; ¶¶ 35-40, 116). Wang further discloses that the impedance information is

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cross-checked and if there is a difference in the impedances are found then the stimulation pattern changes (e.g. ¶¶ 15-16, Claim 64).

23. Regarding claims 53 and 55, Wang discloses that the system and method can be used internally, externally, or with any type of cardiac rhythm management system and is capable of being configured to a thorax (e.g. Figs. 1 & 3a.). Wang further discloses that the system has a telemetry circuit ("330").

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

26. Claims 22, 37 and 54 are rejected under 35 U.S.C. 103(a) as being obvious over Scheiner in view of Hine et al. (U.S. Pat. 7,142,919 hereinafter "Hine").

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27. Sheiner discloses the claimed invention as discussed in detail above, but Sheiner fails to disclose an impedance monitoring system that includes two activity sensors. However, Hine discloses a lead system that utilizes impedance, transthoracic impedance, and acceleration in variable pacing (Col. 6, ll. 1-67). Hine, further discloses the use of two accelerometers with intersecting axis's (Col. 23, ll. 43-56; Col. 26, ll. 15-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the impedance monitoring system as taught by Scheiner, with the impedance and acceleration system as taught by Hine, since such a modification would provide the impedance system with more accurate way to determine activity for providing improved pacing during physical activity.

28. Claims 7-8, 12, 17-18, 21-24, 27, 35-37, 41-43, 47-50, and 54 are rejected under 35 U.S.C. 103(a) as being obvious over Wang in view of Hine et al. (U.S. Pat. 7,142,919 hereinafter "Hine").

29. Wang discloses the claimed invention as discussed in detail above, but Wang fails to disclose an impedance monitoring system that includes an activity sensor. However, Hine discloses a lead system that utilizes impedance, transthoracic impedance, and acceleration in variable pacing (Col. 6, ll. 1-67). Hine, further discloses the use of two accelerometers with intersecting axis's (Col. 23, ll. 43-56; Col. 26, ll. 15-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the impedance monitoring system as taught by Wang, with the impedance and acceleration system as taught by Hine, since such a

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modification would provide the impedance system with more accurate way to determine activity for providing improved pacing during physical activity.

Conclusion

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Park et al. (U.S. Pat. 6,928,324).- Discloses that thoracic impedance is proportional to ventilation rate (Col. 15, ll. 27-34; Col. 21, ll. 30-43).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rex Holmes
Examiner
Art Unit 3762

GEORGE R. EVANISKO
PRIMARY EXAMINER

1/29/03